

REMARKS

Claims 1 to 71 are pending in this application. Claims 7, 10 to 12, and 35 to 63 are withdrawn from consideration. Claims 1 to 6, 8, 9, 13 to 34, and 64 to 71 are rejected. No claims are herein amended. Applicants request reconsideration of the rejections in light of the following remarks.

Summary of the Rejections

The claims are rejected, as follows:

- Claims 1 to 6, 8, 9, 13 to 34, and 64 to 71 are rejected under 35 U.S.C. § 112, first paragraph; and
- Claims 1 and 2 are rejected under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1 to 6, 8, 9, 13 to 34, and 64 to 71 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly non-enabled. Specifically, the Office is challenging the enablement of the hydrates and solvates of the compounds of Formula I. Applicants respectfully traverse the rejection because the specification enables a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and to use the invention commensurate in scope with claims 1 to 6, 8, 9, 13 to 34, and 64 to 71 without undue experimentation.

In order to establish a *prima facie* case of non-enablement, the following must be established by the Patent Office:

1. a rational basis as to
 - a. why the disclosure does not teach; or
 - b. why to doubt the objective truth of the statements in the disclosure that purport to teach;
2. the manner and process of making and using the invention

3. that correspond in scope to the claimed invention
4. to one of ordinary skill in the pertinent technology,
5. without undue experimentation, and
6. dealing with subject matter that would not already be known to the skilled person as of the filing date of the application.

Any rejection under 35 U.S.C. § 112, second paragraph, for lack of enablement, must include evidence supporting each of these elements. Applicants respectfully submit that the Office has failed to meet its burden of establishing a *prima facie* case of non-enablement.

It has been consistently held that the first paragraph of 35 U.S.C. § 112 requires nothing more than *objective* enablement. Furthermore, a specification that teaches how to make and use the invention in terms which correspond in scope to the claims *must* be taken as complying with the first paragraph of 35 U.S.C. § 112, *unless* there is reason to doubt the objective truth of the statements relied upon therein for enabling support. *Stahelin v. Secher*, 24 U.S.P.Q.2d 1513, 1516 (B.P.A.I. 1992) (citing *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (C.C.P.A. 1971)). “[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to ... back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.” *In re Marzocchi*, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). In the instant application, the only evidence provided by the Office is the assertion that none of the working examples formed hydrates or solvates and that the forming specific solvates can be unpredictable. However, evidence does not establish that solvates cannot be formed by the synthetic methods described in the application. Accordingly, applicants respectfully submit that the Office has not met its burden.

The basis of the enablement rejection appears to be the fact that synthesizing specific hydrates and solvates is unpredictable and that applicants have not provided enough guidance to a skilled artisan to prepare the hydrates and solvates. Applicants traverse this basis because in fact under certain synthetic conditions the solvates of the compounds of Formula I will be naturally formed because water or a solvent is present during the synthesis. Skilled artisans recognize this fact. Applicants are simply claiming the active compound (the

compound of Formula I) and its solvates, hydrates, and pharmaceutically acceptable salts because they have provided enablement for these compounds. No undue experimentation would be required produce hydrates and solvates. Under certain synthetic conditions, a skilled artisan would expect hydrates or solvates of the compounds of Formula I would form. Applicants have enabled what they have claimed.

A lack of working examples with respect to the synthesis and isolation of specific solvates does not automatically make a patent non-enabling. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 U.S.P.Q. 409 (Fed. Cir. 1984). Additionally, 35 U.S.C. § 112 does not demand a “working example,” and an application cannot be fatally defective merely because it lacks one. *In re Long*, 151 U.S.P.Q. 640 (C.C.P.A. 1966); *In re Honn et al.*, 150 U.S.P.Q. 652 (C.C.P.A. 1966); *In re Bartholome et al.*, 156 U.S.P.Q. 20 (C.C.P.A. 1967); and *Ex parte Kenega*, 189 U.S.P.Q. 62 (Pat. Off. Bd. App. 1974).

Because a skilled artisan would recognize how to make and use the solvates of the compound of Formula I, applicants respectfully submit that there is not a reasonable basis for rejecting the claims. Accordingly, applicants respectfully request reconsideration and withdrawal of this rejection of claims 1 to 6, 8, 9, 13 to 34, and 64 to 71 under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1 and 2 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for using the term “contains” in the phrases “saturated or unsaturated which contains” and “heterocyclic or heteroaryl ring contains.” Applicants traverse the rejection.

Applicants submit that it is clear what is meant by the term “contains” and the skilled artisan would have no difficulty understanding what is meant by the term as it is used in each phrase. The term has been used intentionally in an open-ended manner because other atoms and substituents may be present in the moieties. For example, in addition to the heteroatoms of nitrogen, oxygen, and sulfur, the heterocyclic and heteroaryl rings may and will contain

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other atoms (necessarily carbon and hydrogen but possibly others). Therefore, such open ended language as “contains” is appropriate. Applicants thank the Examiner for his suggestion of other terminology (*i.e.*, “has”), but applicants believe that the case law supports that “having” and “containing” have generally been construed in the same manner and are open-ended.¹

Applicants submit the use of the term “contains” is definite. Accordingly, applicants respectfully request reconsideration and withdrawal of this rejection of claims 1 to 6, 8, 9, 13 to 34, and 64 to 71 under 35 U.S.C. § 112, first paragraph.

Conclusions

Applicants request reconsideration and withdrawal of the rejections of claims 1 to 6, 8, 9, 13 to 34, and 64 to 71. If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (404) 459-5642.

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¹“Having:” *In re Certain Slide Fastener Stringers*, 216 USPQ 907 (Ct. Int’l Trade 1981); *Compro-Frank Corp. v. Valk Mfg. Co.*, 216 USPQ 531 (E.D. Pa. 1982); *Lampi Corp. v. Am. Power Prods., Inc.*, 228 F.3d 1365, 56 USPQ.2d 1445, 1453-54 (Fed. Cir. 2000)

“Containing:” *Mars, Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 71 USPQ 1837 (Fed. Cir. 2004).